

Please type a plus sign (+) inside this box →

PTO/SB/08A (10-96)
 Approved for use through 10/31/99. OMB 0651-0031
 Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
	Application Number		
	Filing Date		
	First Named Inventor	Herman F. Staats	
	Group Art Unit	1647	
	Examiner Name	R. Landsman	
	Attorney Docket Number	180/102/2	
Sheet	1	of	2

U.S. PTO
 09/874103
 06/05/01

U.S. PATENT DOCUMENTS						
Examiner Initials ¹	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
↓	A1	4,935,343		Allison et al.	06/19/1990	
	A2	5,008,374		Nakai et al.	04/16/1991	
	A3	5,266,311		Cerrati et al.	11/30/1993	
	A4	5,334,379		Pillai et al.	08/02/1994	
	A5	5,342,614		Nakai et al.	08/30/1994	
	A6	5,342,615		Nakai et al.	08/30/1994	
	A7	5,371,204		Nakai et al.	12/06/1994	
	A8	5,437,988		Bellini et al.	08/01/1995	
	A9	5,474,899		Lisi	12/12/1995	
	A10	5,543,140		Nakai et al.	08/06/1996	
	A11	5,702,698		Nakai et al.	12/30/1997	
	A12	5,728,571		Velati Bellini et al.	03/17/1998	
	A13	5,210,072		Chedid et al.	05/11/1993	
	A14	5,206,014		Nencioni et al.	04/27/1993	

FOREIGN PATENT DOCUMENTS								
Examiner Initials ¹	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
BC	B1	WO	88/06843		Cerreti et al.	09/22/1988		
↓	B2	WO	91/01143	✓	Pillai et al.	02/07/1991		
	B3	WO	91/13986		Maliszewsk	09/19/1991		
	B4	WO	92/03574		Andrews et al.	03/05/1992		
	B5	WO	94/00491		Bartfai et al.	01/06/1994		
	B6	NL	93/01929		Billiau	10/17/1994		
	B7	EP	810285		Dorssers et al.	12/03/1997		
	B8	EP	761688		Landon	03/12/1997		
	B9	WO	96/07673		Larsen et al.	03/14/1996		
	↓	B10	EP	353516		Velati Bellini et al.	09/14/1994	

Examiner Signature		Date Considered	8/19/03
-----------------------	--	--------------------	---------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



+

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Kn wn

Application Number

Filing Date

First Named Inventor

Herman F. Staats

Group Art Unit

1646

Examiner Name

R. Landsman

Attorney Docket Number

180/102/2

Sheet	2	of	2
-------	---	----	---

1985 U.S. PTO
07/874103
06/05/01

[illegible][illegible]

Date _____

Considered

8/19/03

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.**

+

Please type a plus sign (+) inside this box →

PTO/SB/08B (10-96)

Approved for use through 10/31/99. OMB 0651-0031

Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

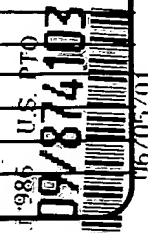
INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

Complete if Known

Application Number
Filing Date
First Named Inventor Herman F. Staats
Group Art Unit 1647
Examiner Name R. Landsman
Attorney Docket Number 180/102/2



OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
BL	C1	SARKAR, "Drug Metabolism in the Nasal Mucosa," Pharm. Res., p. 1-9, (1992).	X
	C2	PONTIROLI ET AL., "Nasal Administration of Glucagon and Human Calcitonin to Healthy Subjects: A Comparison of Powders and Spray Solutions and of Different Enhancing Agents," European Journal of Clinical Pharmacology, p. 427-430, (1989).	X
	C3	ELSON ET AL., "Mucosal Adjuvants," Handbook of Mucosal Immunology, Academic Press, Inc. (San Diego), p. 391-402, (1994).	X
	C4	REISS, T. AND STRAUSS, E., "Vaccines-Patenting Dynamics of a Powerful Healthcare Tool," Exp. Opin. Ther. Patents, Vol. 8 (No. 8), p. 951-958, (1998).	X
	C5	ELSON, "Cholera Toxin as a Mucosal Adjuvant," Mucosal Vaccines, Academic Press (New York), p. 59-72, (1996).	X
	C6	JENKINS, "Mucosal Vaccine Delivery," Exp. Opin. Ther. Patents, p. 255-262, (1999).	X
	C7	LILLARD ET AL., "Lymphotactin Acts as an Innate Mucosal Adjuvant," J. Immuno., Vol. 162 (No. 4), p. 1959-1965, (1999).	X
	C8	MRSNY, "Adjuvants and Delivery Issues Related to Immunization: A Survey of the Recent Patent Literature," J. of Drug Targeting, Vol. 6 (No. 4), p. 243-249, (1998).	X
	C9	GIANNARINI ET AL., "Decrease of Allergen-specific T-cell Response Induced by Local Nasal Immunotherapy", Vol. 28, Clinical and Experimental Allergy, pp. 404-412 (1998).	
	C10	POCKLEY ET AL., "In Vivo Adjuvant Effect of Interleukins 5 and 6 on Rat Tear IgA Antibody Responses", Vol. 73, Immunology, pp. 19-23 (1991).	
	C11	O'HAGAN, "Recent Advances in Vaccine Adjuvants for Systemic and Mucosal Administration", Vol. 49, J. Pharm Pharmacol, pp. 1-10 (1997).	

Examiner Signature

[Signature]

Date Considered

8/19/03

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box →

PTO/SB/08B (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known	
		Application Number	
		Filing Date	
		First Named Inventor	Herman F. Staats
		Group Art Unit	1647
		Examiner Name	R. Landsman
Attorney Docket Number	180/102/2		
Sheet	2	of	2

09/874103
 06/05/01
 98 U.S. PTO

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
BL	C12	KRAMER ET AL., "Cytokine Mediated Effects in Mucosal Immunity", Vol. 73, Immunology and Cell Biology, pp. 389-396 (1995).	
	C13	NASH ET AL., "Recombinant Cytokines as Immunological Adjuvants", Vol. 71, Immunology and Cell Biology, pp. 367-379 (1993).	
	C14	LIN ET AL., "Present Status of the Use of Cytokines as Adjuvants with Vaccines to Protect Against Infectious Diseases", Vol. 21, Clinical Infectious Diseases, pp. 1439-49 (1995).	
	C15	LI ET AL., "Nasal Tolerance to Experimental Autoimmune Myasthenia Gravis: Tolerance Reversal by Nasal Administration of Minute Amounts of Interferon- ", Vol. 87 Clinical Immunology and Immunopathology, pp. 15-22 (1998).	
	C16	MARINARO ET AL., "Oral but Not Parenteral Interleukin (IL)-12 Redirects T Helper 2 (Th2)-type Responses to an Oral Vaccine Without Altering Mucosal IgA Responses", Vol. 185, No. 3, J Exp. Med., pp. 415-427 (February 3, 1997).	
	C17	XIAO ET AL., "Suppression of Acute and Protracted-relapsing Experimental Allergic Encephalomyelitis by Nasal Administration of Low-dose IL-10 in Rats", Vol. 84, Journal of Neuroimmunology, pp. 230-237 (April 15, 1998) (Abstract).	
	C18	FUJIMARA ET AL., "Effect of Thromboxane A2 Antagonists on Bronchial Hyperresponsiveness Induced Immediately after Interleukin-8 Inhalation in Guinea-pigs", Vol. 122, British Journal of Pharmacology, pp. 1015-1020 (1997).	
	C19	CALLARD ET AL., "The Cytokine Facts Book", Academic Press, Harcourt and Co., Publishers, pp. 241 (1994).	
	C20	ABRAHAM ET AL., "Intranasal Immunization with Liposomes Containing IL-2 Enhances Bacterial Polysaccharide Antigen-Specific Pulmonary Secretory Antibody Response", Journal of Immunology, Vol. 149, No. 11, pp. 3719-3726 (1992).	
	C21	GAO ET AL., "BHV-1 Glycoprotein 1 and Recombinant Interleukin 1B Efficiently Elicit Mucosal IgA Response", Vaccine, Vol. 13, No. 9, pp. 871-877 (1995).	

Examiner Signature	<i>[Signature]</i>	Date Considered	8/19/03
--------------------	--------------------	-----------------	---------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

English language translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.**